NUTRICIA

flocare® Infinity™

INSTRUCTIONS FOR USE

For enteral use only

Read this manual before using the pump

BE-NL • INHOUD

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Figure 1

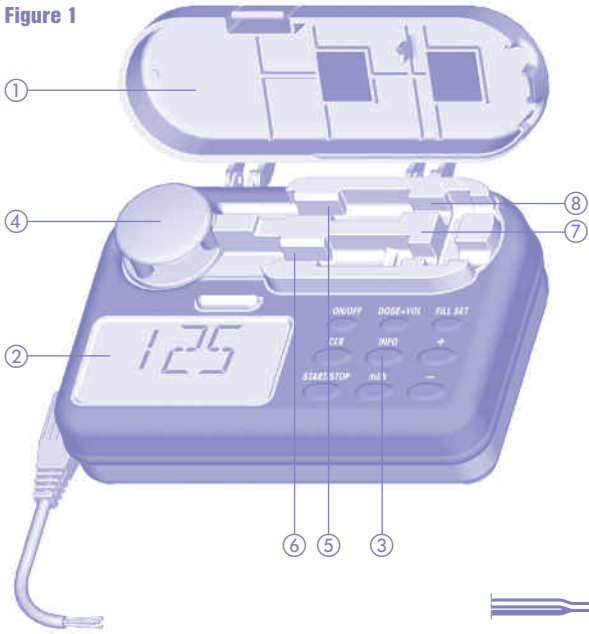
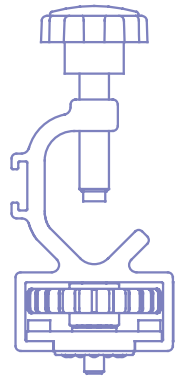


Figure 3



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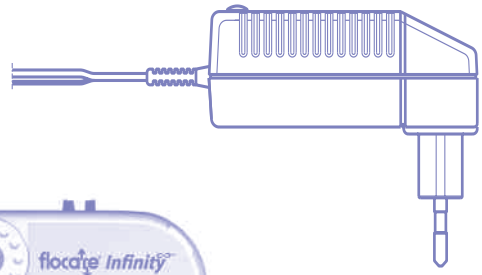


Figure 2

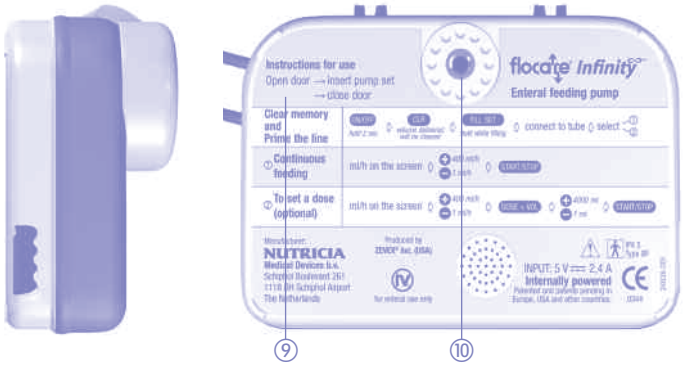


Figure 5a

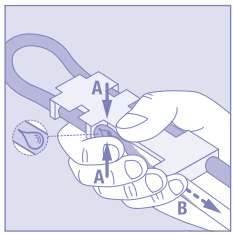


Figure 5b

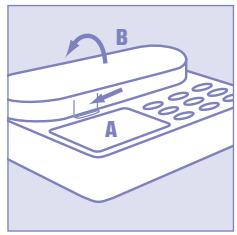


Figure 5c

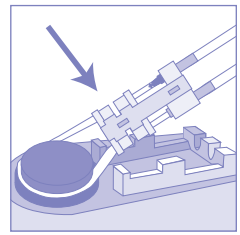
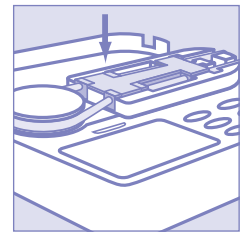


Figure 5d



BE-NL
POMPSPECIFICATIES:

Fig. 1:
① Pompdeur
② Scherm (LCD)
③ Toetsenbord
④ Rotor
⑤ Stroomopwaartse druksensor
⑥ Stroomafwaartse druksensor
⑦ Vakje voor pompset
⑧ Luchtsensor

Fig. 2:
⑨ Gebruiksaanwijzing
⑩ Bevestigingspunt voor paalklem
⑪ Aansluiting voor adapter

Fig. 3: Paalklem

Fig. 4: Adapter

Fig. 5a-5d: De pompset vullen en inbrengen

DE-AT-CH-LU
KOMPONENTENLISTE:

Fig. 1:
① Pumpentüre
② Anzeigefeld (LCD)
③ Tastatur
④ Rotor
⑤ Vorgeschalteter Drucksensor
⑥ Nachgeschalteter Drucksensor
⑦ Anschluss für das Pumpsegment
⑧ Luftsensor

Fig. 2:
⑨ Bedienungshinweise
⑩ Anschluss für Schraubhalterung
⑪ Buchse für den Netzanschluss

Fig. 3: Schraubhalterung

Fig. 4: AC/DC Adapter/Ladegerät

Fig. 5a-5d: Einführung des Pumpsegments

ES
LISTA DE COMPONENTES:

Fig. 1:
① Compuerta de la bomba
② Panel indicador (LCD)
③ Teclado
④ Rotor
⑤ Sensor de presión ascendente
⑥ Sensor de presión descendente
⑦ Receptáculo para insertar el sistema
⑧ Sensor del aire

Fig. 2:
⑨ Instrucciones de uso
⑩ Receptáculo para el fijador del polo
⑪ Toma para la conexión a la unidad cargadora de enchufe

Fig. 3: Fijador del polo

Fig. 4: Cargador

Fig. 5a-5d: Inserción del equipo de bomba

FR-BE-CH-LU
LISTE DE COMPOSANTS:

Fig. 1:
① Porte
② Ecran (LCD)
③ Clavier
④ Rotor
⑤ Capteur de pression amont
⑥ Capteur de pression aval
⑦ Site insertion cassette
⑧ Détecteur d'air

Fig. 2:
⑨ Instructions d'utilisation
⑩ Site insertion support
⑪ Connexion de l'adaptateur

Fig. 3: Support

Fig. 4: Chargeur

Fig. 5a-5d: Insertion de la tubulure

IT-CH
ELENCO DEI COMPONENTI:

Fig. 1:
① Sportello pompa
② Visualizzatore a cristalli liquidi (LCD)
③ Tastiera
④ Rotore
⑤ Sensore della pressione in ingresso
⑥ Sensore della pressione in uscita
⑦ Ricettacolo per l'inserto del set
⑧ Sensore dell'aria

Fig. 2:
⑨ Istruzioni per l'uso
⑩ Ricettacolo per il sistema di fissaggio alla piantana
⑪ Connettore per l'alimentatore

Fig. 3: Sistema di fissaggio alla piantana

Fig. 4: Caricabatterie

Fig. 5a-5d: Inserimento del set

PT
LISTA DE COMPONENTES:

Fig. 1:
① Porta
② Ecrã (LCD)
③ Teclado
④ Rotor
⑤ Sensor de pressão ascendente
⑥ Sensor de pressão descendente
⑦ Receptor para colocação do sistema
⑧ Sensor de ar

Fig. 2:
⑨ Instruções de utilização
⑩ Receptor para colocação do suporte
⑪ Conexão para o carregador

Fig. 3: Suporte

Fig. 4: Carregador

Fig. 5a-5d: Colocação do sistema de alimentação na bomba

UK-IE
LIST OF COMPONENTS:

Fig. 1:
① Pump door
② Display panel (LCD)
③ Keypad
④ Rotor
⑤ Upstream pressure sensor
⑥ Downstream pressure sensor
⑦ Receptacle for pump insert
⑧ Air sensor

Fig. 2:
⑨ Instructions for use
⑩ Receptacle for pole clamp
⑪ Socket for connection to the plug charger unit

Fig. 3: Pole clamp

Fig. 4: Charger

Fig. 5a-5d: Filling and Insertion of the pump set

ORDERING INFORMATION

Flocare® Infinity™ pump Western Europe **corporate code 35676**
Flocare® Infinity™ Charger
Pole clamp
Instructions for use

Optional accessories
Please refer to your local Nutricia contact for availability of Flocare® Infinity™ accessories, as there are: feeding sets, carry bag, PDMS/data cable, nurse call, service suitcase and other.

MANUFACTURER

Nutricia Medical Devices b.v.
Schiphol Boulevard 261
1118 BH Schiphol Airport
The Netherlands

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INTRODUCTION

- The Flocare® Infinity™ pump is a small, lightweight pump for both portable and bedside use. The pump is based on the rotary peristaltic principle and is intended for enteral use only.

PREPARATION

- Check the integrity of the pump. Do not use the pump if it is damaged. If a technical failure occurs or if the pump is dropped, the pump should be checked by a qualified technician.
- Do not use the pump in areas where there is a risk of explosions e.g. in the presence of flammable anaesthetics.
- If the pump has been stored for any period of time, it should be plugged into the mains to recharge the battery before commencing enteral feeding. The battery will be completely charged after approximately 6 hours.
- The Flocare® Infinity™ pump should only be used in combination with the appropriate Flocare® Infinity™ pump set! (consult your local Nutricia sales representative for information on availbale pump sets).
- This pump operates in any orientation, making it ideal for ambulatory use.
- Check the position of the feeding tube, as advised by your healthcare professional, before commencing tube feeding.
- Pump fed patients should be regularly monitored and supervised. Specific patient groups require consistent and controlled administration of enteral nutrition as well as simultaneous application of medication (e.g. insulin administration). In these cases, regular and frequent checks, as determined by the attending healthcare professional, should be carried out to ensure correct administration of nutrition throughout the therapy period. Using the Infinity™ pump's DOSE function is recommended in these cases (see section "To set a Dose").
- For bedside use, the multi-position pole clamp (figure 3) can be attached to the pump with the screw provided. The pump can be fixed in any position (rotatable in 360°).

SERVICE AND WARRANTY

The manufacturer recommends an inspection of the pump at an authorised service centre every 2 years. Only authorised personnel should perform service work on Infinity™ pumps. Please contact your local Sales Organisation / Nutricia Subsidiary for all service and repair of pumps (see address at the back of the booklet).

Limitations of warranty

Solely for the benefit of the original buyer/user, Nutricia Medical Devices B.V, warrants all new Flocare® Infinity™ pumps, of its manufacture to be free from defects in material and workmanship, excluding normal wear and tear, and will replace or repair, at its service facility or other location designated by Nutricia Medical Devices B.V, any Flocare® Infinity™ pump returned to it within thirty-six (36) months of original purchase by the buyer/user. Such repair or replacement shall be free of charge.

Nutricia Medical Devices B.V warrants to the original buyer/user, all repaired or replaced pumps to be free from defects in material and workmanship and will replace or repair such products, at its service facility or other location designated by Nutricia Medical Devices B.V. Such repair or replacement shall carry a warranty of ninety (90) days from the date of repair or replacement or the balance of the new pumps warranty as described above, whichever is greater.

THIS WARRANTY APPLIES ONLY TO FLOCARE® INFINITY™ PUMPS MANUFACTURED BY NUTRICIA MEDICAL DEVICES B.V AND IS THE ONLY WARRANTY GIVEN WITH RESPECT TO THE PUMPS. NO WARRANTIES IMPLIED IN LAW, INCLUDING, BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR PARTICULAR PURPOSE, SHALL APPLY. NUTRICIA MEDICAL DEVICES B.V WILL BE LIABLE, IN ANY EVENT, ONLY FOR THE PURCHASE PRICE OF THE DEFECTIVE PRODUCT, BUT NOT FOR ANY CONSEQUENTIAL DAMAGES.

This Warranty may not be modified, amended or otherwise changed, except by a written document properly executed by a corporate officer of Nutricia Medical Devices B.V

THE WARRANTY IS VOID IF THE FLOCARE® INFINITY™ PUMP IS SUBJECT TO ABUSE, ACCIDENT, ALTERATION, MODIFICATION, TAMPERING, MISUSE OR THE UNAUTHORIZED REPAIR OR SERVICE IN ANY WAY WITHOUT PRIOR AUTHORIZATION FROM NUTRICIA MEDICAL DEVICES B.V. IN ANY EVENT, NUTRICIA MEDICAL DEVICES B.V.'S LIABILITY SHALL NEVER EXCEED THE ORIGINAL PURCHASE PRICE OF THE PUMP AND SHALL NOT EXTEND TO ANY CONSEQUENTIAL LOSS OR DAMAGE.

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OPERATING INSTRUCTIONS

INSERTION OF THE FLOCARE® INFINITY™ PUMP SET

- Connect the set to the feed container as instructed on the packaging of the Flocare® Infinity™ pump set. Remove the dust cap from the step connector.
- The Flocare® Infinity™ pump sets are equipped with an “automatic free-flow protection”, as a consequence the set has no roller clamp.
  Fill the pump set completely with feed by gently pinching on the side of the cassette that is marked with a drop (point A on figure 5a) or fill the pump set with help of the pump (see paragraph: filling the pump set).
- Open the pump door by pressing up on the lower wall and rotating the door upwards at the same time (see figure 5b).
- Position the looped section of the silicone tubing around the rotor.
  Stretching lightly, (see figure 5c) seat the cassette into the pump (see figure 5d).
- Close the pump door.

SWITCHING “ON”

ON/OFF

For proper pump operation, make sure the pump door is closed prior to switching the pump on. Press the “ON/OFF” key for 2 seconds.
The pump beeps and carries out a short self test, showing the pump serial number in 8 digits. Verify that all display segments and symbols are active as shown in figure 6 (see next page).
The pump displays the total volume delivered since the memory was cleared and switches in the hold mode ready for programming.

SWITCHING “OFF”

ON/OFF

Press the “ON/OFF” key and keep it pressed for 2 seconds. A continuous alarm will be heard and the pump switches off.
The feeding program (installed parameters) and total volume administered since the last clearance will be retained in the pump’s memory.
If the pump shuts down due to low battery voltage, the memory will be retained for 24 hours.

“HOLD” MODE

START/STOP

To temporarily pause the pump, or switch into “hold” mode whilst operating, press the “START/STOP” key once. Three beeps are heard and the run symbol disappears.
The programmed flow rate (ml/h), volume (DOSE=VOL) and the administered volume (ml) are retained.

The “hold” mode is used to temporarily stop the flow of feed:
- to change the feeding program (installed parameters),
- to change the feed container,

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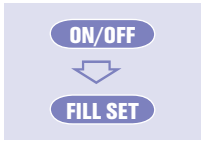
- to administer medication without switching the pump off,
- to silence an alarm and correct problems.

After 3 minutes a two tone audible alarm sounds and the message “PUSH STRT” appears in the display. Press “START/STOP” to stop the alarm and to extend the hold mode by a further 3 minutes or press “START/STOP” twice (3 beeps will be heard) to resume programmed settings.

FILLING THE PUMP SET



The FILL SET function offered by the Infinity pump is used to fill a (new) feeding set with nutrition (or water as the case may be). When the FILL SET function runs all alarms are deactivated helping avoid alarms being inadvertently triggered (e.g. air alarm). The FILL SET function should only be used to fill an empty (air-filled) feeding set. Use of the FILL SET function at any other time may cause the pump to incorrectly calibrate. When the FILL SET function is initiated the pump will calibrate to the giving set.

When the pump is in the hold mode:
Press and hold the “FILL SET” key for 2 seconds to activate the “FILL SET” maneuver. Release the button as soon as the pump generates a beep and starts pumping at a flow rate of approx. 700ml/h. During this maneuver the message “FILL SET” appears in the display. The pump will automatically stop when the Flocare® Pack Infinity™ pump set is completely filled with feed. However this “FILL SET” maneuver can at anytime be stopped by pushing the “FILL SET” key a second time. The pump will return to the hold mode when the “FILL SET” maneuver is complete or stopped.

DISPLAY

The pump has a liquid crystal display (L.C.D.) with large alphanumeric characters, smaller symbols, words and a back light.
The following information can be found in the display:

- Flow rate (ml/h), volume (ml), is displayed through the large characters.
  Words below describe what the number relates to (rate, dose or volume).
  The pump also displays messages, for example “end of dose” will appear when the pump has finished delivering a single feed dose.

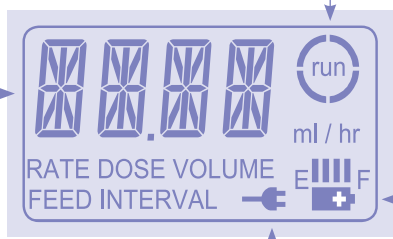


Figure 6

- The arcs around the run symbol rotate when the pump is running.
- The remaining battery capacity (see paragraph: battery operation).
- The wall plug symbol indicates that the charger is plugged in.

The back light of the display turns off 10 seconds after the last key is pressed.
The back light will switch on for 10 seconds when the charger is connected to the mains.

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PROGRAMMING THE PUMP

- The Flocare® Infinity™ pump can be used for continuous or dose feeding.
- Insert the pump set in the pump, switch the pump on and fill the pump set when necessary (see paragraph: filling the pump set).
- The display shows the total volume delivered since the pump was last cleared.
- If necessary clear the volume delivered by pressing the “CLR” key.
- The last installed flow rate (ml/h) is now displayed.
- The pump is now in the “hold” mode and is ready for programming.

CONTINUOUS FEEDING

- Adjust the flow rate (ml/h) if required by using the “+” or “-” key. Hold either key down to change rapidly.
- If another parameter is indicated in the LCD, it will be necessary to first press the “ml/h” key followed by the “+” or “-” key to set the flow rate.
- The flow rate ranges from 1 - 400 ml/h in 1ml increments.
- The flow rate slows down and stops shortly at 50 - 125 - 250 ml/h.
- Press the “DOSE=VOL” key and make sure the value is put at 0 ml indicated by the word “CONT”. This means the pump will run in a continuous mode.
- Start the pump by pressing “START/STOP”.
- The arcs around the word “run” start rotating.
- The flow rate (ml/h) is displayed whilst functioning.

TO SET A DOSE

From the hold mode, with the last flow rate (ml/h) displayed in the LCD:

- Set the flow rate by pressing the “+” or “-” key.

If another parameter is displayed:

- Press first the “ml/h” key followed by “+” or “-” key to adjust the flow rate. The flow rate can be set between 1 and 400 ml/h, with increments of 1ml.
- Press the “DOSE=VOL” key and install the volume to be administered with the “+” and “-” key. The range goes from 1 - 4000 ml, with steps from 1ml.
- Start the pump by pressing “START/STOP”.

During functioning the following parameters can be found in the display:

- By pressing the “ml/h” key the “flow rate” is displayed.

- By pressing the “INFO” key the total volume since the memory was cleared will be visualized.

When the required volume or dose has been delivered, “END OF DOSE” will appear and the pump will beep (or mute, depending upon the pumps’ configuration (see paragraph: set up mode).

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TO CHANGE THE FEEDING PROGRAM DURING FUNCTIONING

- Press the “START/STOP” key to pause the pump.
- Change the program by pressing the required key (ml/h or DOSE=VOL) and adjust using the “+” or “-” keys.
- Restart the pump by pressing the “START/STOP” key again.

CLEARING THE MEMORY

All parameters and values can be cleared one after the other in the following way:

- Press “START/STOP” to pause the pump.
- Select the parameter that needs to be cleared.
- Press the “CLR” key to clear the memory. The parameter or value returns to its default value:
  ml/h = 0 ml/h
  VOL = cont = No dose set. Pump will feed continuously until feed container is empty or pump is stopped
  INFO = 0 ml = Volume delivered is cleared

In order to keep a clear overview of the daily amount of feed delivered, clear the total volume delivered as each daily feeding schedule is started, as follows:

- Switch the pump “ON”
- Immediately after the self-test the pump displays total volume delivered.
- Press the “CLR” key. The total volume delivered returns to “0 ml”.
- The pump displays the previous programmed flow rate (ml/h).
- The pump is in the “HOLD” mode ready for programming.

- When another feeding program needs to be started, or the pump will be used for another patient, all settings (rate and dose) can be returned to default and the volume delivered can be set at zero by simply pressing the “CLR” key and keeping it pressed for 2 seconds.

BATTERY OPERATION

- The Flocare® Infinity™ pump is equipped with a Lithium-ion battery.
- The battery symbol in the display is automatically replaced by the plug symbol when the adapter is plugged in. The “fuel gauge” then indicates that the battery is charging by displaying the segments in an ascending low to high pattern starting with the leftmost segment.
  This pattern continuously repeats while the pump is charging.

- To check the status of the battery, disconnect the charger from the pump and turn the pump on. The bars between E and F (E=Empty, F=Full) represent the “fuel gauge” of the battery. Each bar is approximately 1/4 of a full battery charge. If 2 bars appear the battery is half full and remaining operating time is approximately 12 hours at a flow rate of 125 ml/h.

- In case of power failure the pump automatically switches to battery powered operation.
- When during functioning the last block is gone, the battery symbol will blink to indicate that there is approximately 1 hour of charge left. The display will flash “BATT” every 3 seconds, alternating with the active display and the pump will beep every 2 seconds to remind the user of the low battery charge condition. Plug in the charger to continue to run and recharge the battery.
- As the battery level decreases the pump may not be able to deliver tube feeds at rates greater than 300 ml/h, even though some battery capacity remains. The pump will alarm and indicate “BATT”. If this happens, either

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recharge the battery or select a lower rate to complete the feed cycle.

- In case of battery failure, caused by, for example, an excessive temperature condition (which may resolve itself with time) or by a complete battery failure, the E, F and battery symbol will flash. Turn the pump “off” and contact your healthcare provider or refer the pump to service.

CONNECTION TO AN EXTERNAL ALARM SYSTEM

The power connector at the side of the pump offers the option of connecting the pump to an external alarm system or Patient Data Monitoring System (PDMS).

- The Flocare® Infinity™ Nurse Call (corporate code 35752) enables connection to an external alarm system. This external alarm system may be with open or closed contact. Follow the instructions for use of the Flocare® Infinity™ Nurse Call to connect the pump.
- The Flocare® Infinity™ PDMS Cable (corporate code 35776) enables connection to an external PDMS system. Follow the instructions for use of the Flocare® Infinity™ PDMS Cable to connect the pump.

ALARM FUNCTIONS AND SAFETY FEATURES

In case any of the problems listed on the problem solver chart occur, the pump delivers an audible and visual alarm and stops working. The back light of the LCD automatically switches on.
Exception to this is the low battery alarm “BATT”, in this situation the pump continues working.
Action in the event of an alarm:
Check the type of alarm displayed by the large display characters.

- Press the “START/STOP” key to stop the audible and visual alarm.
- Correct the cause of the alarm as described in the table.
- Start the pump again by pressing “START/STOP”.

The problem solver chart on the next page gives a clear explanation of the alarms.

MAINTENANCE

Cleaning:

- Always unplug the pump prior to cleaning to avoid electric shock hazard.
- On a regular basis thoroughly clean all surfaces of the pump (including the sensors and rotor) with warm soapy water, a 5% bleach solution in water, or a multipurpose disinfectant cleaner.
- The Flocare® Infinity™ pump may be rinsed by holding under a stream of warm, clean water. Do not submerge the pump!
- Always maintain the rollers on the rotor in a clean state to ensure they spin freely.
- The adaptor normally does not require cleaning. When desired, a dry or slightly damp cloth may be used to clean the outside surface of the adaptor. Make sure the adaptor is disconnected from the wall outlet.

Safety notes:

- The manufacturer recommends an inspection of the pump at an authorised service centre every 2 years.
- If any fault occurs during use, or if the pump is dropped, it should be checked by authorised technical personnel prior to use.
- Replace the Flocare® Infinity™ pump set every 24 hours to maintain delivery accuracy and prevent the growth of harmful bacteria. Dispose of Flocare® Infinity™ disposable sets properly, as required by local law.
- Do not use the Infinity alarm systems to trigger actions related to secondary (electrical) medical devices (e.g. a volumetric or syringe pump).
- Do not use pump functions (e.g. the fill set function) for any other purpose than described in this manual, as this may cause the pump to incorrectly calibrate.

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PROBLEM SOLVER CHART

Always follow the instructions below in case a problem occurs.
Using methods other than those described may cause the pump to function incorrectly.

Condition	Cause	Correction
NO SET	• The set is not fitted or wrongly fitted in the pump. • The pressure sensor area is dirty	• Stop the alarm by pressing "START/STOP" • Insert the Flocare® Infinity™ cassette into the pump as indicated on the blister packaging and close the door. • Restart the pump. • Clean the sensors, reinsert the cassette in the pump and restart the pump.
PUSH STRT	• The pump has been untouched in hold mode for 3 minutes or more.	• Stop the alarm and prolong the hold mode with another 3 minutes by pressing "START/STOP" key. • Program the pump and start it by pressing the "START/STOP".
END OF DOSE	• The pump administered the installed dose = volume.	• Turn the pump off by pressing the "ON/OFF" key and hold it during 2 seconds or • Clear the memory of the total volume administered (see paragraph: clearing the memory), reprogram a new feeding schedule and start the pump by pressing "START/STOP".
PROG	• No flow rate is installed. Flow rate = 0 ml/h	• Make sure the correct flow rate is programmed.
DOOR	• The door is not correctly closed.	• Make sure the door is properly closed prior to starting a feeding program.
AIR	• The air sensor detected an empty pump set. • The air sensor area is dirty. • The feeding set is not inserted correctly.	• Replace the empty feeding reservoir and continue feeding. If necessary prime the set. • Make sure the air sensor is clean. • Make sure the feeding set is properly inserted in the pump.
BATT the pump remains working	• The battery capacity is too low. The pump is not able to deliver highly viscous fluids at high flow rates with the present charge level of the battery.	• Connect the adaptor to the pump and mains and charge the pump for approx. 6 hours. During charging the pump can be used.
Battery, "E" and "F" flashing	• Battery failure.	• Turn the pump "off", contact your healthcare provider or refer the pump to service.
FILL SET	• The pump is priming the set.	• Press the "FILL SET" key another time to stop the pump and bring it back in the hold mode.
OCC IN	• The pump detected an upstream occlusion between the pump and the feeding bag. • The pressure sensor area is dirty.	• Stop the alarm by pressing the "START/STOP" key. • Remove the feeding set out of the pump and check the permeability by flushing the line. • Re-insert the feeding set in the pump and restart. • Clean the sensors, reinsert the cassette in the pump and restart the pump.
OCC OUT	• The pump detected a downstream occlusion between the pump and the patient. • The pressure sensor area is dirty.	• Stop the alarm by pressing the "START/STOP" key. • Check the permeability of the feeding tube by aspirating liquid via the medication port. • Clean the sensors, reinsert the cassette in the pump and restart the pump.
OCC OUT (repeated)	• Calibration not yet completed on the current feeding set	• Stop the alarm by pressing the "START/STOP" key. • Start the pump by pressing the "START/STOP" key and let it run only briefly. • Stop the pump by pressing the "START/STOP" key insuring that there has been no occlusion out alarm. • Remove the feeding set from the pump and reinsert the feeding set in the pump. • Restart the pump by pressing the "START/STOP" key.

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Condition	Cause	Correction
LOCK	• Only the current feeding schedule is allowed for this patient. Another feeding program is not allowed by your healthcare professional.	• The programming feature is blocked in the set up mode of the pump. Ask your healthcare professional to modify this setting.
ER01 - ER99	• The self test detected an electronic error	• Turn the pump “off”, make sure the pump door is closed and switch the pump back “on”. If the error persists, contact your healthcare provider or refer the pump to service.
No plug symbol visible, while the pump is connected to the mains.	• The wall outlet doesn’t work. • The adaptor is damaged.	• Connect the pump to another wall outlet. • Contact your healthcare professional or Nutricia subsidiary to replace the adaptor.

SET UP MODE

The set up mode is used
- to set the alarm level,
- to lock the keypad,
- to switch the audible alarm off when a dose is administered,
- to switch the light of the LCD permanently on when connected to the mains,
- to enable connection with a Nurse call or Patient Data Monitoring System (PDMS).

This set up mode may only be entered by healthcare professionals and authorised personnel trained to use this application of the pump.
The patient or his/her relatives without permission of the physician, dietician, nurse or other licensed practitioner, may not change the settings of the set up mode.

TO SET THE ALARM LEVEL

Switch the pump “on” while holding the “+” key down. The pump enters the set up mode.
First the alarm level can be set:
“BEEP HIGH” (+) or “BEEP LOW” (-)
Use the “+” or “-” key to change the setting from “high” to “low” or from “low” to “high”.

TO LOCK THE KEYPAD

Press in the set up mode the “FILL SET” key to switch to the next setting:
“UNLK” the keypad (-) or “LOCK” the keypad (+). In the “LOCK” mode the feeding program of the pump can no longer be changed.
Use the “+” or “-” key to change the setting from “lock” to “unlk” or vice versa.

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TO MUTE WHEN DOSE DONE

Press in the set up mode the “FILL SET” key to switch to the next setting:
“BEEP WHEN DONE” (+): the pump will give an alarm when the dose is administered or “MUTE WHEN DONE” (-): the pump will not give an alarm after administering the dose. Use the “+” or “-” key to change the setting from “beep when done” to “mute when done” or vice versa.

TO SWITCH LIGHT ON

Press in the set up mode the “FILL SET” key to switch to the next setting:
“LITE ON” (+) the light of the LCD remains on when the pump is connected to the mains. “LITE OFF” (-) the light of the LCD switches off after a few seconds even if connected to the mains. Use the “+” or “-” key to change the setting from “lite on” to “lite off” or vice versa.

TO CONNECT WITH NURSE CALL OR PDMS

Press in the set up mode the “FILL SET” key to switch to the next setting:
“OUTP PDMS” (+) to connect with a Patient Data Monitoring System. “OUTP NRSE” to connect with a NURSE CALL system. Use the “+” or “-” key to change to setting from “OUTP PDMS”, to “OUTP NRSE” or “OUTP OFF” and vice versa.

Press the “ON/OFF” key and hold it down for 2 seconds to exit the SET UP mode. The settings are automatically saved.

TECHNICAL SPECIFICATIONS

- This Flocare® Infinity™ pump in combination with the adapter and the Flocare® Infinity™ Nurse Call are designed to EN 60601-1-2, EN 61000-3-2, EN 61000-3-3, RTCA DO-160D standards for electromagnetic emissions and immunity and are in compliance with Directive 93/42/EEC.

CE 0344

- IEC 601: Class II Medical Device Directive: Class IIa
- Microprocessor controlled
- BF Equipment
- Charger: input 100-240V AC / 50-60 Hz / 0.4A Max.
  output 5 V DC 2.4 A
- Battery: internal rechargeable Lithium ion battery, 3.6 V DC 2000 mAh
- Battery capacity: 24 hours at 125 ml/h
- Jet waterproof: IPX 5
- IPX 5: Splash water proof: Water jets from any direction shall have no effect on the pump.

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- Dimensions: 140 x 95 x 35 mm
- Weight: approx. 392 g
- Accuracy flow rate: ±5,0% with appropriate Flocare® Infinity™ pump set
- Humidity: Operation mode: 30% to 75% noncondensing
  Storage: 10% to 95 % noncondensing
- Temperature: Operation mode: +5°C to +40°C
  Storage and transportation: -20°C to +65°C
- Atmospheric pressure: Operation mode: 70-106 kPa
  Storage and transportation: 50-106 kPa
- Occlusion detection pressure: Upstream occlusion: -34 kPa (tolerance 21 kPa)
  Downstream occlusion: 83 kPa (tolerane 21 kPa)
- Air bubble detection: The amount of air, that must pass the air sensor before the air alarm is activated, varies from 0.5 to 1 ml which relates to an air bubble with an approximate length in the silicone pump segment of 6 - 13 cm.
- The Flocare® Infinity™ can safely be operated on commercial aircraft.
- The use of other accessories, adaptors and cables than listed within this manual may result in increased emissions or decreased immunity of the equipment of the Flocare® Infinity™ pump.
- Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the accompanying documents.
- Portable and mobile RF communications equipment (cellular telephones) can affect medical electrical equipment. If the Flocare® Infinity™ pump is used adjacent to or stacked with other equipment, the pump should be observed to verify normal operation.
- In case of pump scrapping, always notify your Nutricia sales unit of the pumps serial number. Pump scrapping should always occur according to local legislation.

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APPENDIX A: GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer's Declaration – Electromagnetic emissions

The Flocare® Infinity™ enteral feeding pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Flocare® Infinity™ enteral feeding pump should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF Emissions CISPR 11	Group 1	The Flocare® Infinity™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Flocare® Infinity™ is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's Declaration – Electromagnetic immunity

The Flocare® Infinity™ enteral feeding pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Flocare® Infinity™ enteral feeding pump should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	≤ 6 KV contact ≤ 8 KV air	≤ 6 KV contact ≤ 8 KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electric fast transient/burst IEC 61000-4-4	≤ 2 KV for power supply lines ≤ 1 KV for input/ output lines	≤ 2 KV for power supply lines ≤ 1 KV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	≤ 1 KV differential mode	≤ 1 KV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines. IEC 61000-4-6	161 V_{ac} for 0,5 s 95 V_{ac} for 100 ms 0 V_{ac} for 10 ms 0 V_{ac} for 5 s	161 V_{ac} for 0,5 s 95 V_{ac} for 100 ms 0 V_{ac} for 10 ms 0 V_{ac} for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Flocare® Infinity™ requires continued operation during power mains interruptions, it is recommended that the Flocare® Infinity™ enteral feeding pump be powered from an uninterruptible power supply of battery.

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Recommended separation distances between portable and mobile RF communications equipment and the Flocare® Infinity™ enteral feeding pump

The Flocare® Infinity™ enteral feeding pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Flocare® Infinity™ can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Flocare® Infinity™ as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 KHz to 80 MHz $d = 0,12\sqrt{P}$	80 MHz to 800 MHz $d = 0,12\sqrt{P}$	800 MHz to 2,5 GHz $d = 0,23\sqrt{P}$
0,01	0,01	0,01	0,02
0,1	0,04	0,04	0,07
1	0,12	0,12	0,23
10	0,37	0,37	0,74
100	1,17	1,17	2,33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's Declaration – Electromagnetic immunity

The Flocare® Infinity™ enteral feeding pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Flocare® Infinity™ enteral feeding pump should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Flocare® Infinity™, including cables, than the recommended separation distance calculated from the equation applicable toe the frequency of the transmitter: **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	3 Vrms 150 KHz to 80 MHz	$d = 1,17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 Mhz to 2,5 GHz	30 V/m 80 Mhz to 2,5 GHz	$d = 0,12\sqrt{P}$ 80 MHz to 800 MHz $d = 0,23\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 Mhz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measurement field strength in the location in which the Flocare® Infinity™ is used exceeds the applicable RF compliance above, the Flocare® Infinity™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Flocare® Infinity™.

b. Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

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